IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO: CASES IDENTIFIED IN **EXHIBIT A** TO PLAINTIFFS' UNDERLYING MOTION

MDL No. 2327

PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE OR LIMIT THE OPINIONS AND TESTIMONY OF DR. NICOLETTE HORBACH

Plaintiffs hereby submit this Reply Memorandum of Law in support of their Motion to Exclude or Limit the Opinions and Testimony of Defendant Ethicon, Inc.'s ("Defendant") expert Dr. Nicolette Horbach ("Dr. Horbach"). For the reasons discussed herein and in Plaintiffs' Memorandum of Law in Support of their Motion to Exclude or Limit the Opinions and Testimony of Dr. Nicolette Horbach ("Plaintiffs' Memo"), the Court should exclude Dr. Horbach's testimony in it's entirety or should limit Dr. Horbach's testimony to matters in which she is qualified to testify and for which she has provided reliable bases for her opinions.

INTRODUCTION

In order for an expert to testify in front of a jury, the Federal Rules of Civil Procedure require that the expert provide a written report that "must contain a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). The logic behind Rule 26 is simple; if an expert is to testify at trial, the opinions she seeks to offer and the basis for those opinions must be disclosed so that the Court can determine if the opinions are admissible, and so that opposing counsel can test the opinions through cross-examination. If an expert's opinions stem from her review of certain scientific

literature, and the findings in that literature form the basis for the expert's opinions, then the expert is required to disclose that scientific literature under Rule 26. Dr. Horbach failed to do that here, and because of that failure the Court should exclude Dr. Horbach's opinions entirely as the product of faulty methods. Should the Court elect not to exclude Dr. Horbach's opinions entirely, the Court should limit Dr. Horbach's testimony to matters in which she is qualified and has provided a proper basis for her opinions as set forth in Plaintiffs' Motion.

I. Argument

A. Dr. Horbach's Failure to Provide a Proper Basis for Her Opinions Renders Her Methodology Flawed and Her Opinions Unreliable.

Rule 26 requires an expert to provide the basis and reasons for each opinion and Dr. Horbach failed to do so in three dispositive ways. First, Dr. Horbach's report contains citations that consist of only an author's name and a year, and those citations may or may not be on Dr. Horbach's Reliance List or Sources List that were supplied to Plaintiffs. *See*, Pls.' Memo at 4-5. Second, some of the opinions set forth in Dr. Horbach's report contain no citations to the papers that form the bases for those opinions. *Id*. at 5-6. Third, Dr. Horbach's attempt to use her Reliance List as support for her opinions is patently unreliable as she admits in her deposition that she did not review the Reliance List provided to Plaintiffs prior to her deposition, and, further, that she has only reviewed "the bulk" of the material on that Reliance List. Pls.' Ex. E, Horbach 3/25/16 Dep., at 15:1-18. This is improper under Rule 26. As with all evidence, "expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir.2006)(*quoting, Daubert*, 509 U.S. at 596). In order to cross-examine Dr. Horbach on her opinions, however, Plaintiffs must know how the opinions were formed and the bases for the

opinions. That is the purpose of Rule 26, and Dr. Horbach failed to comply with the Rule in her role as Defendants' expert on the TVT Retropubic product.

In their Memo at pages 2-5, Defendants attempt to shift the burden of curing the deficiencies in Dr. Horbach's report to Plaintiffs by arguing that: (1) The Federal Rules do not require citations; (2) Plaintiffs should have questioned Dr. Horbach about the source of each opinion set forth in her 79-page report during her deposition; (3) Dr. Horbach *did* review the materials on her Reliance List, just not the Reliance List itself (even though Defendants' cite to Dr. Horbach's deposition testimony where she unequivocally testified that she only "looked at the bulk of..." the materials on her Reliance List.), and; (4) The opinions expressed in her latest report, "builds off those previous lists of materials" utilized in her prior reports. Each argument fails.

First, it is undisputed that the Federal rules require that an expert provide all opinions and the basis and reasons for them. Fed. R. Civ. P. 26(a)(2)(B)(i). Here, the vast majority of Dr. Horbach's report consists of recitations of scientific literature, but Dr. Horbach does not properly cite to the specific literature that forms the basis of her opinions. This methodology does not comport with the requirements of Rule 26. Second, it would be impossible for Plaintiffs' counsel to elicit each of the bases for Dr. Horbach's opinions during her deposition as Defendants suggest, because Dr. Horbach readily admitted that she had not reviewed the entirety of the materials contained on her Reliance List before coming to her deposition. Pls.' Ex. E, Horbach 3/25/16 Dep., at 15:1-18. Third, in response to Defendants' argument that Dr. Horbach did review the materials on her Reliance List, just not the list itself, this argument is factually flawed. Indeed, it is impossible for Dr. Horbach to *know* that she reviewed the materials on her Reliance List if she has not looked at the Reliance List itself. Further, this argument is

inconsistent with her own sworn testimony in which Dr. Horbach admitted that she only reviewed "the bulk" of the materials on her Reliance List (which, again, she had not reviewed prior to giving that testimony), not *all* of the material. *Id.* Finally, as to Defendants' argument that the opinions expressed in Dr. Horbach's latest report "builds off those previous lists of materials" utilized in her prior reports, this Court has addressed and rejected that very argument, holding:

> I am compelled to comment on the parties' misuse of my previous Daubert rulings on several of the experts offered in this case. The parties have, for the most part, structured their Daubert arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of an expert's opinion based on its reliability and relevance. In other words, the parties have comparatively examined each expert's opinions and have largely overlooked *Daubert's* core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are remiss, *especially when an expert has issued new reports and given additional deposition testimony*.

Winebarger v. Boston Sci. Corp., 2015 U.S. Dist. LEXIS 53892, 10-11 (S.D. W. Va. Apr. 24, 2015)(emphasis added). An expert cannot simply "build off of" prior reports and reliance lists when being proffered in a separate case, and Defendants' citations to a deposition from three years ago where Dr. Horbach testified that she reviewed all of the materials on her reliance list *with regard to a different expert report* do not prove that she did so here. Rule 26 requires that every time an expert is retained to testify, she must come forward with a report that outlines all of her opinions and the basis for those opinions. Dr. Horbach failed to meet those requirements *in these Wave 1 cases* and so her opinions should be excluded entirely.

B. Dr. Horbach's is Not Qualified to Opine on the Physical and/or Clinical Differences between Machine-Cut and Laser-Cut Mesh in Defendants' TVT Retropubic.

Here, Dr. Horbach is offered as an expert on one device: the TVT Retropubic. In her report she offers expert opinions regarding the differences between the laser-cut and machine-cut

mesh used in the TVT Retropubic. Despite her expert opinions on the laser-cut versus machine-cut mesh used in the TVT Retropubic, Dr. Horbach does not even know if she has ever used a TVT Retropubic with laser-cut mesh in her own practice. Pls.' Memo at 8. In Response, Defendants attempt to confuse that important fact by highlighting Dr. Horbach's use of another device that utilizes laser-cut mesh, the Exact, which is not the subject of Dr. Horbach's expert opinions. Def. Memo at 6. Because Dr. Horbach is not offering expert opinions about the Exact device, and because that device is unrelated to the TVT Retropubic device, she has no relevant clinical experience for her opinions and is therefore unqualified to testify about the differences between the laser-cut and machine-cut mesh in the TVT Retropubic device.

Next, Defendants argue that Dr. Horbach's opinions on the differences between machine-cut and laser-cut mesh are supported by her review of scientific literature. Def. Memo at 7. However, Dr. Horbach's expert report related to this opinion does not offer even one reference to any piece of scientific literature in support of her expert opinions on the differences (or lack thereof) between machine-cut and laser-cut mesh in the TVT Retropubic device. *See*, Pls.' Ex. B, Horbach Expert Report, at p. 64-65. Dr. Horbach's opinions on the differences between the laser-cut and machine-cut mesh used in the TVT Retropubic are unreliable and the Court should exclude Dr. Horbach's opinions on this topic at trial.

C. Dr. Horbach Should Not be Allowed to Opine on Degradation of Mesh Based on Her Clinical Experience Because She Utilized Insufficient Methodology in Forming her Opinions.

By her own admission, Dr. Horbach never utilized a microscope powerful enough to see mesh degradation on any of the explanted mesh samples that she studied in her clinical practice. Pls.' Memo at 9-10. Despite that flawed methodology as a backdrop for her degradation opinions, Defendants argue that Dr. Horbach should still be allowed to tell the jury that mesh

does not degrade *in vivo*, because she has "not really" seen any degradation of explanted mesh in her clinical practice. Def. Memo at 8. If allowed, this opinion would do nothing more than confuse and mislead the jury. Further, it would not help the jury as Dr. Horbach has admitted that a very powerful microscope, such as an electron-scanning microscope, is required to see the degradation, and that she was not using the same:

> Q: Do you know whether the microscope you were using was sufficiently powered to see degradation?
>
> A: Probably not since I think most of the degradation reports seem to be more with, you know, scanning electron microscopy or other very specialized type of equipment and/or preparations.

See, Pls.' Memo at 9-10, *see also*, Pls.' Ex. F, Horbach 12/23/15 Dep., at 99:1-7.

Further, in response to Plaintiffs' arguments regarding Dr. Horbach's Materials Science opinions, Defendants' Memo unequivocally states, "she [Dr. Horbach] is only opining on the alleged degradation of mesh." *See*, Def. Memo at 11. However, Dr. Horbach's report contains other Materials Science opinions regarding mesh contraction, mesh design characteristics, and the general safety and suitability of the TVT Retropubic for use as a permanent implant. *See*, Pls.' Memo at 13-15. For the reasons set forth in Plaintiffs' Memo, these opinions should not be admitted at trial and Defendants have not come forward with any argument in their Memo to the contrary. Dr. Horbach's methodology is flawed, her opinions are unreliable, and she should not be allowed to testify on these topics at trial.

D. Dr. Horbach's Device Labeling Opinions are Distinguishable from this Court's Prior Orders Allowing Similar Testimony from other Urogynecologists.

Defendants argue that this Court should allow Dr. Horbach's labeling opinions because, "her opinions speak only to how clinicians would interpret the IFUs, and what problems may arise if the IFU is interpreted incorrectly." Def. Memo at 9. Defendants cite to this Court's

opinion in *Winebarger* with regard to Plaintiffs' expert Dr. Shull for the proposition that Dr. Horbach's labeling opinions should be admitted because they are not "regulatory opinions." Def. Memo at 9-10. This argument misses the mark. Dr. Horbach's opinions are regulatory opinions. Indeed, she opines that: (1) the purpose of Defendant's IFUs/DFUs is "not to provide a complete medical education to the physician about how to perform a mid-urethral sling procedure and/or the properties and risks of using a synthetic material;" (2) that the IFU/DFU provides "adequate information on the device including its use and potential risks for surgeons;" (3) that it is not Defendant's responsibility to teach surgeons how to implant their TVT Retropubic devices; and, (4) that it is not Defendant's responsibility to list all potential surgical risks and benefits for an individual patient in its IFU/DFUs and patient brochures. *See*, Pls. Memo at 11. By alleging that the IFU is "adequate," and setting forth her interpretation of the purpose and required contents of an IFU, Dr. Horbach is providing regulatory opinions that she is not qualified to give and for which she utilizes no applicable industry standards as set forth in Plaintiffs' Memo. Pls.' Memo at 11-13. As such these opinions should be excluded.

Further, Dr. Horbach's opinions on the TVT Retropubic IFU should be excluded because she never even read the IFU before implanting the product in her own practice:

> Q. Before you used the TVT Retropubic device, which you've told us you used for a number of years before you started to use either the TVT Exact or the Boston Scientific sling, did you read the IFU that came with that package?
>
> A: I actually never read the IFU prior to using the package.

Pls.' Ex. F, Horbach 9/24/15 Dep., at 134:24-135:5. If Dr. Horbach does not even look at the IFUs for medical devices that she implants in her patients before she implants them, and in particular for the device that is the subject of her expert report, it seems illogical that she is now qualified as an expert on how the IFU for that device should be interpreted by clinicians who

actually do read the IFU before they use the device. As such her opinions will confuse the jury, are unreliable, and should be excluded.

E. The Court Should Exclude Dr. Horbach's Opinions that Stem from Specific Scientific Literature where She Fails to Provide the Basis for those Opinions.

On pages 5-6 of Plaintiffs' Memo, Plaintiffs identified five examples of Dr. Horbach's opinions that stem from her review of scientific papers, but for which Dr. Horbach failed to identify the source that forms the basis for each of those opinions. Because an expert is required to identify the basis for her opinions under Rule 26, and because Dr. Horbach failed to do so with regard to these opinions, these opinions should be excluded.

CONCLUSION

For each of the reasons set for above, Plaintiffs respectfully request that this Honorable Court preclude Dr. Horbach from offering any opinions at trial, and specifically from offering opinions on the following topics:

1. The physical and clinical differences between machine-cut and laser-cut mesh;
2. The pathological findings of explanted mesh;
3. Medical Device Product Labeling;
4. The Biomaterial properties of mesh; and,
5. Opinions with no identifying source information.

Dated May 16, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on May 16, 2016, a true and correct copy of this Reply was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

/s/ Aimee H. Wagstaff, Esq.